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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,624	04/12/2007	Akihiko Miyamoto	042269	1499
38834 7590 04/15/2010 WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036				
EXAMINER YOUNG, RACHEL T				
ART UNIT 3771		PAPER NUMBER		
NOTIFICATION DATE 04/15/2010		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentmail@whda.com

### Office Action Summary

**Application No.**

10/578,624

**Applicant(s)**

MIYAMOTO, AKIHIKO

**Examiner**

RACHEL T. YOUNG

**Art Unit**

3771

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 January 2010 and 08 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- \_\_\_\_\_ Paper No(s) Mail Date 5/8/06

## DETAILED ACTION

### *Amendment*

1. This office action is responsive to the amendment filed on 1/6/2010 and 1/8/2010. As directed by the amendment: claim 1 has been amended, no claims have been canceled, and new claims 2-3 have been added. Thus, claims 1-3 are presently pending in the application.

### *Specification*

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to **a single paragraph** on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, lines 11-12 recites "an inhalation has been correctly performed, a sound is produced from the reed". However it is unclear as to how the correctness of an inhalation is being measured. Is the user breathing in air at a certain flow rate, which makes the reed sound? Would the reed not sound if the user inhaled too greatly? Is that still correct? Please clarify.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinkade (5,062,422) in view of Nowaki et al. (4,809,692) and MacRae et al. (2002/0046751).

Regarding claim 1, in fig. 7 Kinkade discloses a main unit 12 having a resilient material (Col. 2, ll. 12-13) tube (where 12 is pointing in fig. 1, tube passageway can be seen in fig. 8) used to aid an inhaler (Col. 1, ll. 10-13), and a horn-shaped junction 6 at a lower portion of the main unit; an engagement portion (where 10 is pointing in fig. 1) which is provided at an upper portion of the main unit, the engagement portion including and constituted of left and right projections, each having a holding member 2 at an end thereof. Kinkade is silent regarding that a reed is fitted into a right side of the main unit. However, in fig. 1 Nowacki teaches a whistle 72 provided on the right side of the main unit (depending on how the device is being held). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kinkade's main unit with a whistle, as taught by Nowacki, for the purpose of providing an audible signal that the user is breathing properly (abstract). The modified Kinkade discloses that when the inhaler aid is joined to a mouthpiece of the inhaler and an inhalation has been correctly performed, a sound is produced from the reed (abstract Nowacki). The modified Kinkade is silent regarding that the main unit is made from a silicon rubber. However, MacRae teaches an adapter body made from synthetic rubber, and preferably of a silicone material (Page 5, para 111). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made

to modify Kinkade's main unit with a silicone rubber material, as taught by MacRae, for the purpose of providing a flexible and comfortable mouthpiece.

Regarding claim 2, the modified Kinkade of claim 1 discloses the claimed invention, but is silent regarding a powder medicament. However, MacRae teaches a powder medicament (page 6, para 115). ). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kinkade's main unit with a powder medicament, as taught by MacRae, for the purpose of providing medicament to a user.

Regarding claim 3, the modified Kinkade of claim 1 discloses the claimed invention.

### ***Response to Arguments***

8. Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new grounds of rejection.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Foley (5,042,467) to a medication inhaler with a reed, Puderbaugh et al. (6,026,807) to a spacer with a reed, and Malone (2002/0104531) to a pediatric inhalation device with a whistle. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS**

**MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **RACHEL T. YOUNG** whose telephone number is (571)270-1481. The examiner can normally be reached on mon-thurs 7 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RACHEL T YOUNG/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771